

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT HUNTINGTON**

UNITED STATES OF AMERICA,

Plaintiff,

v.

Civil Action No. 3:18-CV-01289

**MATTHEW MALLORY,
COMMONWEALTH ALTERNATIVE
MEDICINAL OPTIONS, LLC,
GALE KALE, GRASSY RUN
FARMS, LLC, their agents,
servants, assigns, attorneys, and all
others acting in concert with the
named defendants,**

Defendants.

**REPLY IN SUPPORT OF MOTION FOR RELIEF FROM THE GENERAL ORDER
HOLDING CIVIL MATTERS IN ABEYANCE**

COMES NOW, Defendants Matthew Mallory (“Mallory”) and Commonwealth Alternative Medicinal Options, LLC (collectively “CAMO Defendants”), by and through counsel, and pursuant to this Court’s January 9, 2019 Order, hereby files this Reply in support of their Motion for Relief from the General Order Holding Civil Matters in Abeyance.

As its caption would suggest, the Motion was a request for relief from the General Order’s abeyance of civil matters involving the United States of America. In it, the CAMO Defendants emphasized that the passage of time has changed the circumstances underlying the Court’s September 17, 2018 Order, in which the Court expressly reserved ruling upon the pivotal legal issue in this civil action. In that Order, the Court observed that the “several week” period during which the CAMO Defendants were permitted to harvest, dry, and process the subject industrial

hemp offered the Court “the opportunity to consider and rule on the question of law that is central to the merits of the case with little harm to Defendants[.]” (ECF No. 20 at 2 (emphasis added).)

Now, nearly four months later, that harm is looming. With full respect for the demands on this Court’s time and attention, the CAMO Defendants simply are asking for a ruling. Absent the resolution of the pending dispositive motions, the CAMO Defendants face significant financial hardship. Moreover, continued delay effectively grants the United States of America (the “Government”) the victory that it seeks – to prohibit the Defendants from harvesting and profiting from this particular crop. All of which is why the CAMO Defendants requested that the abeyance be lifted to permit the Court to swiftly resolve the determinative issue: whether the transport of industrial hemp across state lines violates the Controlled Substances Act.

The Government opposes this request because additional delay inures to its benefit; there is little risk to the Government in continuing its substantially unjustified efforts to damage a lawful business. Yet, the Memo. in Opposition. is bereft of any discussion as to why the General Order’s abeyance should not be lifted. Instead, the Government uses this pleading to repeat its misguided legal theories, to advance a couple of new (and equally puzzling) ones, and to urge the court to further delay the its ruling pending the outcome of an unrelated appeal. Having no reasonable basis in the law, these efforts should be rejected.

As detailed in CAMO Defendants’ Motion, the hemp must be moved from the West Virginia facility by January 13, 2019 in order to permit the CAMO Defendants to complete processing the industrial hemp and fulfill its contractual obligations. The inability to do so could result in substantial and lasting negative impacts on the CAMO Defendants.

I. The actions of the CAMO Defendants were in full compliance with applicable law.

Irrespective of retroactivity, unfounded allegations about the Food and Drug Administration, or the Government's request for additional delay, the law "that existed when the conduct took place" dictates the same result: the Defendants complied with the law and this case should be dismissed. Fundamentally, the Government misunderstands the impact of the Agricultural Act of 2014, 7 U.S.C. 5490 ("Farm Bill") and the Consolidated Appropriations Act, 2018, Public Law No. 115-141 § 729, which expressly sanction the CAMO Defendants' lawful conduct and which expressly preclude the Government from expending federal dollars to frustrate the CAMO Defendants participation in the Pilot Program.

It bears repeating that the Government's claims for relief are premised upon purported violations of West Virginia's Pilot Program, namely the strained allegation that that the West Virginia Pilot Program *required* the CAMO Defendants "to identify international sources for their cannabis seeds" and that they "failed to follow this requirement of the WVDA pilot program," thereby violating federal law. (Compl. ¶¶ 28-29.) Yet, as the CAMO Defendants have previously fully briefed and argued, and as confirmed by the West Virginia Department of Agriculture's September 11, 2018 communication to the Government, (ECF No. 19-2), the CAMO Defendants are in material compliance with the Pilot Program.

To make its case, therefore, the Government adds a requirement to section 5490 that simply is not there: a purported ban on transporting industrial hemp across state lines. This prohibition appears nowhere in the statute and the Government's repeated assertions to the contrary do not make it so.

Moreover, the Government has never explained why the Consolidated Appropriations Act for Fiscal Year 2016 ("Omnibus Law") does not preclude this litigation altogether. In 2016,

Congress eliminated any lingering confusion about the contours of the 2014 Farm Bill and the legality of industrial hemp by including protective language in the Omnibus Law. Since extended on March 23, 2018, the Omnibus Law sets forth:

None of the funds made available by this Act or any other Act may be used—
 (1) in contravention of section 7606 of the Agricultural Act of 2014 (7 U.S.C. 5940); or
 (2) to prohibit **the transportation, processing, sale, or use of industrial hemp, or seeds** of such plant, that is grown or cultivated in accordance with subsection section 7606 of the Agricultural Act of 2014, **within or outside the State** in which the industrial hemp is grown or cultivated.

Consolidated Appropriations Act, 2018, Public Law No. 115-141 § 729
<https://www.congress.gov/bill/115th-congress/house-bill/1625/text> (emphasis added).

In other words, the Omnibus Law prohibits federally-appropriated units, including the United States Attorney for the Southern District of West Virginia, from expending federal appropriations to interfere with or otherwise frustrate the intrastate or interstate transportation of industrial hemp grow or cultivated as part of a Farm Bill-authorized agricultural pilot program. *See also* W. Va. Op. Atty. Gen., Jan 11, 2019 (finding the corresponding provisions of Public Law No. 115-141 restricting federal law enforcement agencies from interfering with state-sanctioned medical marijuana applies to “most forms of federal criminal law enforcement, including the Drug Enforcement Administration, the Federal Bureau of Investigation, and the offices of all United States Attorneys.”). This prohibition applies to the transportation of Farm Bill industrial hemp whether transported within **or outside** the state in which it was grown or cultivated.¹ Public Law No. 115-141 § 729.

¹ Additionally, the Omnibus Law also precludes this action because the Government has not alleged – and could not prove – that the **Kentucky** seeds were not cultivated, transported, processed, or sold in accordance with the 2014 Farm Bill. According to the Government’s own allegations, CAMO Defendants acquired the industrial hemp seeds at issue in this action from Hickman Seed & Grain Company, LLC (“Hickman”) in Clinton, Kentucky. (*See* Compl. at ¶ 29.) Under the Farm Bill and Omnibus Law, the seeds were federally legal industrial hemp parts when present with Hickman in Kentucky, and the Government has offered no

All told, the law that existed when the “conduct took place” is clear: Defendants did not violate the CSA and the Omnibus Law specifically prohibits this litigation. Accordingly, there are no reasonable bases in the law for the theories propounded by the Government to justify its prosecution of this case.

II. The FDCA does not preclude the production of CBD oil.

In another attempt to further muddy the waters, the Government asserts – wrongly – that it only now has learned that the industrial hemp at issue is being processed into CBD isolate or CBD oil. In fact, the CAMO Defendants informed the Court and the Government of this fact over two months ago, in its November 2, 2018 SEALED MATERIALS: Notice Under Seal Regarding Industrial Hemp, ECF No. 47. Putting aside the feigned surprise at this revelation, the more disturbing assertion is the Government’s corresponding argument that CBD is “illegal except as specifically permitted by the Food Drug and Cosmetic Act (“FDCA”), 21 U.S.C. § 301, *et seq.*, and the authority of the Commissioner of the Food and Drug Administration (“FDA”).” (Memo. In Opp., ECF 57 at 3.) However, the CAMO Defendants are not regulated by the FDA and the assertion that the production of CBD oil violates FDCA is simply wrong.

The 2018 Farm Bill did in fact legalize industrial hemp, including its “extracts, cannabinoids and derivatives.” Public Law No. 115-334, § 297A (emphasis added). Although the Government does attach a press article in support of its theory of “illegality”, the content or statements contained therein cannot overcome the unambiguous language of a federal statute. As a result, the Government resorts to misrepresentations of the scope of the FDA’s jurisdiction here,

evidence or legal arguments to suggest otherwise. As a result, these seeds remained legal during the course of their transportation to West Virginia. Their entry into West Virginia did not, in any way, deprive them of their status as industrial hemp grown or cultivated pursuant to a Farm Bill-authorized agricultural pilot program. Thus, even if the Government could demonstrate that the CAMO Defendants violated the Pilot Program – and even if that mattered – the Omnibus Law still precludes this action.

especially in its specious reference to the FDA’s approval of pharmaceutical drug Epidiolex.² (Memo in Opp. at 3.)

The reality is that the Government, as the master of its own case, has not premised any request for relief on such downstream conduct, instead focusing exclusively on the acquisition of industrial hemp seeds from Kentucky. Indeed, by the Government’s own admission, all relevant conduct necessary to the resolution of this case occurred long before the 2018 Farm Bill was signed on December 20, 2018. (*See* Memo. in Opp. at 2.) Regardless, the Government cannot point to any legal authority to support the proposition that CAMO Defendants are precluded from processing the hemp to produce pure CBD isolate from the same. Nor has the Government presented any evidence that the CAMO Defendants’ production of pure CBD isolate violates any federal law. And with good reason, since such production or related transactions were lawful in the fall in 2018 and most certainly remain lawful following the passage of the 2018 Farm Bill.

Instead, the Government attempts to aggrandize the FDA’s authority to regulate certain ingestible products into a wholesale ban on producing pure CBD isolate, as well as the jurisdiction to regulate the cultivation of industrial hemp. Or in other words, the Government now suggests that this Court should enjoin lawful activity that produces a lawful product, if a possible

² Obviously, the FDA retains jurisdiction over the approval of pharmaceutical drugs and other topical and ingestible products. *See* 21 U.S.C. § 331. Yet, CBD oil and industrial hemp-CBD products are permissible dietary supplements and ingredients under the FDCA, as amended by the Dietary Supplement Health and Education Act of 1994 (DSHEA), Pub. L. No. 104-417. Generally, the FDCA does not regulate dietary supplements which includes a “product . . . intended to supplement the diet that” contains the extract of “an herb or other botanical” that “is not represented for use as a conventional food or as a sole item of a meal or diet” and is labeled as a dietary supplement. 21 U.S.C. §§ 321(ff). As such, they are not subject to the approval process utilized by the FDA for allowing new pharmaceutical drugs – like Epidiolex – into the market. Epidiolex is a “drug” approved to treat seizures and falls squarely within the jurisdiction of the FDA. *Id.* at §§ 321(g) (drug is defined as “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease”), 331.

downstream use of that product could violate certain federal regulations governing public marketing and labeling. This argument is substantially unjustified and should be ignored.

III. The Court possesses inherent discretion to deny the requested relief.

As noted above, because the conduct of the CAMO Defendants was entirely lawful under the 2014 Farm Bill, there is little need to entertain the Government's strained arguments about whether the 2018 Farm Bill applies retroactively. Still, it is jarring to watch the Government insist that the full weight of the United States of America should be brought to bear against a private business that seeks to grow, cultivate, sell, and transport a legal product.

Regardless of whether the 2018 Farm Bill applies retroactively, however, its passage would seem to implicate this Court's discretionary authority to withhold the requested declaratory and injunctive relief for prudential reasons. The doctrine of "prudential mootness" allows courts to determine that "regardless of constitutional mootness, a case is moot because the court cannot provide an effective remedy and because it would be imprudent for the court to hear the case." *Alt v. U.S. E.P.A.*, No. 2:12-CV-42, 2013 WL 4520030, at *8 (N.D.W. Va. Apr. 22, 2013) (citing *United States v. (Under Seal)*, 757 F.2d 600, 603 (4th Cir. 1985)).

In determining whether to apply the doctrine of prudential mootness, the U.S. Court of Appeals for the Fourth Circuit has applied the following standard:

"In *United States v. W.T. Grant Co.*, 345 U.S. 629 (1953), the United States Supreme Court explained that although discontinuance of conduct sought to be enjoined will not usually suffice to prevent injunctive relief, such relief is inappropriate if the defendant can demonstrate that *there is no reasonable expectation that the wrong will be repeated in the future*. What is more, the party seeking the injunction "must satisfy the court that relief is needed. The necessary determination is that there exists some cognizable danger of recurrent violation, something more than the mere possibility which serves to keep the case alive."

Alt, 2013 WL 4520030, at *8 (quoting *NLRB v. Greensboro News & Record, Inc.*, 843 F.2d 795, 798 (4th Cir.1988) (emphasis added)). Here, even assuming the Government had a reasonable

basis to allege a violation of law, there is little danger of such a violation recurring after the passage of the 2018 Farm Bill. Given the impossibility of any alleged wrong being repeated, considerations of prudence weigh heavily against granting the Government its requested relief.

IV. The Government’s request for delay - *Palomo Farms* case is entirely irrelevant to this case.

Finally, the Government’s last-ditch request to further delay this Court’s ruling is entirely consistent with the balance of its conduct in this case: disingenuous, misleading, and with no reasonable basis in the law. According to the Government, the “Fourth Circuit is presently considering many of the same issues raised by the Mallory defendants in the appeal pending in Palomo Farms, LLC/Hemport v. U.S. Drug Enforcement Agency, 2018 WL 2768676 (E.D.N.C. June 7, 2018), appeal filed, No. 18-1766 (4th Cir. July 9, 2019).” A cursory review of the *Palomo* case, however, reveals the Government misapprehends (or mischaracterizes) the underlying facts and the legal position that the Government itself has taken in that case. First, that case involves the importation of cannabis seeds from overseas, rather than an interstate purchase from Kentucky; for all of its perils, traversing the Big Sandy River is legally and factually distinguishable from the international importation in *Palomo*. More importantly, however, that case was decided exclusively on jurisdictional grounds and does not raise any of the same issues implicated here. Noting that the Drug Enforcement Agency’s denial of the plaintiff’s importation permit application should be treated as a final agency decision, the district court dismissed the plaintiff’s request for injunctive relief, holding that it was “without subject matter jurisdiction to consider plaintiff’s challenges to the agency decision as any such challenge must be brought in the appropriate court of appeals.” *Palomo Farms, LLC/Hemport*, 2018 WL 2768676, at *3. That was the only decision reached by the district court and is the only issue properly before the Court of Appeals. Brief of

Appellant Palomo Farms, LLC/Hempport, *Palomo FARMS, LLC/Hempport*, v. *U.S Drug Enforcement Administration*, No. 18-1766, ECF 11 (4th Cir. Oct. 30, 2018); *see also* Brief of the United States, No. 18-1766, ECF 18 (4th Cir. Nov. 30, 2018). In short, the resolution of *Palomo* has no impact on the instant case.

CONCLUSION

Based on the foregoing, Defendants Matthew Mallory and Commonwealth Alternative Medicinal Options, LLC respectfully request the Court grant CAMO Defendants' Motion for Relief from the General Order Holding Civil Matters in Abeyance, grant CAMO Defendants' Motions to Dismiss, and hold that any and all remaining motions are rendered moot.

Respectfully submitted,

/s/ Carte P. Goodwin

Carte P. Goodwin (WVSB #8039)

Elise McQuain (WVSB #12253)

FROST BROWN TODD LLC

500 Virginia Street, East

Suite 1100

Charleston, WV 25301

Phone: 304-345-0111 | Fax: 304-345-0115

Email: cgoodwin@fbtlaw.com

emcquain@fbtlaw.com

Philip A. Reale, II (WVSB #11372)

Law Office of Philip A. Reale, PLLC

300 Summers Street, Suite 980

Charleston, WV 25301

Phone: 304-342-1891

Fax: 304-342-1893

Email: philip@wvreale.com

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT HUNTINGTON**

UNITED STATES OF AMERICA,

Plaintiff,

v.

Civil Action No. 3:18-CV-01289

**MATTHEW MALLORY,
COMMONWEALTH ALTERNATIVE
MEDICINAL OPTIONS, LLC,
GARY KALE, GRASSY RUN
FARMS, LLC, their agents,
servants, assigns, attorneys, and all
others acting in concert with the
named defendants,**

Defendants.

CERTIFICATE OF SERVICE

I, Carte P. Goodwin, hereby certify that on this day, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the following counsel of record:

Fred B. Westfall, Jr.
Assistant United States Attorney
Attorney for the United States
P.O. Box 1713
Charleston, WV 25326
Phone: 304-345-2200
Fax: 304-347-5443
Fred.westfall@usdoj.gov
Counsel for USA

R. Booth Goodwin II
Tammy J. Owen
GOODWIN & GOODWIN, LLP
300 Summers St., Suite 1500
Charleston, WV 25301
Telephone: (304) 346-7000
Facsimile: (304) 344-9692
rbg@goodwingoodwin.com
tjo@goodwingoodwin.com
*Counsel for Gary Kale and Grassy
Run Farms, LLC*

Dated this 11th day of January 2019.

/s/ Carte P. Goodwin

Carte P. Goodwin (WV Bar No. 8039)

0140198.0711053 4829-6470-3877v1